

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated December 8, 2006 (hereinafter Office Action) have been considered. Claims 1-60 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-8, 11-15, 18-24, 27, 34-36, 41, 44, 45, 48, 50, and 53-58 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,235,246 to *Weiss* (hereinafter "*Weiss*") in view of U.S. Patent No. 6,148,230 to *KenKnight* (hereinafter "*KenKnight*").

Three criteria must be met to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Each of the Applicant's independent claims 1, 18, 27, 44, 48, 50, and 53 recite surface electrodes as structure or recite the use of surface electrodes.

The Applicant respectfully submits that one of ordinary skill in the art would understand, particularly in light of the Applicant's specification, that "surface electrodes", as recited in the Applicant's claims, does not refer to implanted electrodes or electrodes otherwise used within a patient's body. For example, the Applicant's specification states that "the use of the surface electrodes allows the patient not to be subjected to surgery before he/she is determined to be a candidate for the subcutaneous defibrillation system." (Page 30, Lines, 21-23; emphasis added).

Furthermore, surface electrodes are recognized and understood in the art as electrodes that are not implanted or otherwise used within a patient's body, particularly in light of the Applicant's specification. For example, U.S. Patent No. 6,754,517 recites "an outer surface electrode (122) to be arranged against a point on the person's skin." (Abstract). Also, U.S. Patent No. 7,043,308 recites "a system and method of providing electrical

stimulation via the skin of a patient, by means of an inventive surface electrode.” (Col. 1, Lines 8-10). In addition, U.S. Patent No. 5,176,676 recites “a flexible surface electrode for carrying current to and from the skin of a human body.” (Col. 1, Lines 6-8). The Applicant respectfully submits that these references illustrate that one of ordinary skill in the art would understand a surface electrode to be an electrode that is not implanted or otherwise used within a patient’s body, at least within the context of the Applicant’s specification.

The Applicant respectfully submits that both of the *Weiss* and *KenKnight* references only disclose the use of subcutaneous electrodes and do not contemplate the use of surface electrodes.

Weiss discloses an epicardial lead with an insertion assembly for attaching the lead to the heart wall. (Abstract). *Weiss* discloses that the leads can be tested on various areas of the heart wall before being permanently attached to the heart wall. (Col. 5, Lines 1-29). *Weiss* does not disclose, or suggest using, surface electrodes, as all electrodes disclosed by *Weiss* require contact with the heart or at least insertion into the body proximate the heart.

KenKnight discloses a cardiac monitoring device and a plurality of subcutaneous cardiac sensing electrodes electrically connected to the monitoring device. (Abstract). *KenKnight* states that “subcutaneous sensing electrodes described herein are positioned on the thorax of the patient, preferably on the left side and on the ventral surface (that is, on the chest).” (Col. 2, Lines 41-44). The Applicant respectfully submits that even though *KenKnight*’s subcutaneous sensing electrodes are “positioned on the thorax,” these sensing electrodes are nevertheless subcutaneous electrodes that are implanted below the surface of the skin. (See Col. 3, Lines 8-33).

The Applicant respectfully submits that *Weiss*’ heart wall contacting electrodes and *KenKnight*’s subcutaneous electrodes are not surface electrodes. Therefore, neither of these references teach or suggest the use of surface electrodes.

Each of the Applicant’s independent claims 1, 18, 27, 44, 48, 50, and 53 each recite surface electrodes as structure or recite the use of surface electrodes.

Moreover, the Applicant's independent claims 1, 44, and 53 each recite, among other features, some variation of determining a surface pacing level relative to a pacing limit using at least two of the surface electrodes.

Also, the Applicant's independent claims 18 and 44 each recite, among other features, some variation of determining one or more subcutaneous electrode implant locations using the selected one or more surface electrode locations.

In addition, the Applicant's independent claims 27 and 50 each recite, among other features, some variation of a pulse generator configured to deliver a pacing stimulus at a stimulus level . . . the plurality of surface electrodes configured for positioning on a thorax of a patient relative to a patient's heart . . . the controller determining acceptable subcutaneous electrode locations based at least in part on detection of capture or non-capture resulting from delivery of the pacing stimulus at the stimulus level.

Respectfully, when "surface electrode" is properly construed as one of ordinary skill in the art would construe this term, there is clearly no teaching or suggestion of at least the above recited claim elements and limitations. For example, because neither *Weiss* nor *KenKnight* contemplate surface electrodes, neither then contemplates determining a surface pacing level or determining a subcutaneous electrode implant locations using a surface electrode. The Applicant respectfully submits that neither *Weiss* nor *KenKnight* provide a teaching or suggestion regarding a relationship between surface pacing and acceptable subcutaneous locations.

Accordingly, the Applicant respectfully submits that *Weiss*, even in combination with *KenKnight*, fails to teach or suggest each and every element and limitation of independent claims 1, 18, 27, 44, 48, 50, and 53.

Each of claims 2-8, 11-15, 19-24, 34-36, 41, 45, and 54-58 depend from one of independent claims 1, 18, 27, 44, and 53, respectively. Independent claims 1, 18, 27, 44, and 53 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent

claims 1, 18, 27, 44, and 53. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 2-8, 11-15, 19-24, 34-36, 41, 45, and 54-58 are not made obvious by *Weiss*, even in combination with *KenKnight*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-8, 11-15, 18-24, 27, 34-36, 41, 44, 45, 48, 50, and 53-58 and notification that these claims are in condition for allowance.

Claims 9, 10, 16, 17, 25, 26, 28-33, 37-40, 42, 43, 46, 47, 49, 51, 52, 59, and 60 are only indicated as being rejected under an obviousness-type double patenting rejection. The Applicant respectfully requests acknowledgement that these claims contain allowable subject matter.

Claims 1-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-57 of U.S. Patent No. 7,047,071.

The Applicant traverses the double patenting rejection. Specifically, the Applicant respectfully submits that the Examiner has not met the burden necessary for sustaining a obviousness-type double patenting rejection. See MPEP § 804(II)(B)(1). For example, the double patenting rejection in the Office Action describes a single scenario outcome and does not relate this to the claims of either of the patent or the current application. The Applicant respectfully submits that from this scenario, it is unclear how the claims are anticipated or obvious in light of one another. Therefore, the Applicant respectfully requests clarification or withdrawal of the obviousness-type double patenting rejection.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been

obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of the Applicant's invention, officially noticed facts, inherent, and the like. In particular, the Applicant does not acquiesce to the Examiner's statements concerning what would be inherent, for at least the reason that these statements are now moot in view of the erroneous construction of the term surface electrodes recited in the Applicant's claimed subject matter. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

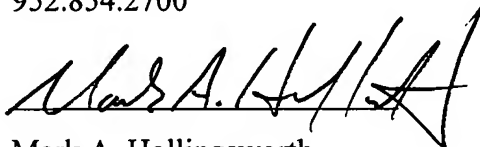
Authorization is given to charge Deposit Account No. 50-3581 (GUID.628PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC
8009 34th Avenue South, Suite 125
Minneapolis, MN 55425
952.854.2700

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By:



Mark A. Hollingsworth
Reg. No. 38,491